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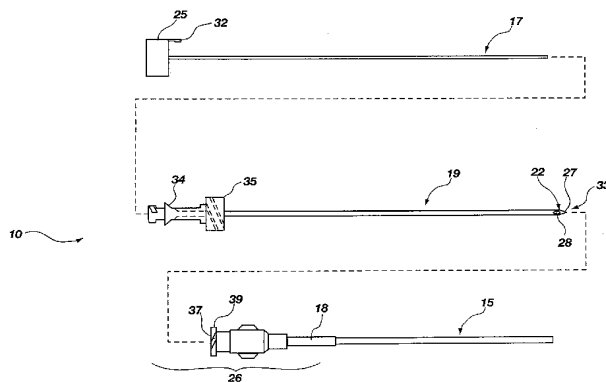


FIG. 1

(57) Abstract: A flow element (50) for use with flexible needles and flexible needle assemblies (10) to minimize flow occlusion within a flexible needle (15) is provided. The flow element (50) is particularly suited for uses with a flexible needle (15) for minimizing incidence of post-dural puncture headache. The flow element (50) includes a body having an internal flow path for conducting a fluid through a flexible needle, and an anti-restriction member (56). The anti-restriction member (56) includes an elongated body (58), a proximal end (70) coupled to the body within the internal flow path, and a distal end (60) for positioning at least a portion of the elongated body within a flexible needle. A flexible spinal needle assembly (10) for minimizing flow occlusion through an internal flow path of a flexible needle (15) by unintended kinking that is potentially caused by ligament or muscle layer movements is also provided, hi other embodiments, a flexible spinal needle assembly (10), a flexible spinal needle assembly kit, a method for installing a flexible spinal needle assembly, and a process for producing a flow element are provided.

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FLOW ELEMENTS FOR USE WITH FLEXIBLE SPINAL NEEDLES, NEEDLE ASSEMBLIES AND METHODS FOR MANUFACTURE AND USE THEREOF

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TECHNICAL FIELD

This invention relates generally to medical devices, and particularly to structures for preventing fluid occlusion in medical needles. It is particularly directed to a flow element for use with flexible needles and flexible spinal needle assemblies, including methods for manufacture and use thereof.

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BACKGROUND

The advantages of continuous administration of spinal anesthesia have long been appreciated by anesthesiologists. Unlike conventional single-shot techniques, continuous spinal anesthesia ("CSA") with an indwelling catheter facilitates the administration of anesthesia over an unlimited period of time and furthermore provides the ability to carefully control the level of the block by administering repeated small, incremental doses of anesthetic. As compared to continuous epidural anesthesia, which has become widely used as a substitute for spinal anesthesia, CSA generally requires far smaller quantities of a drug to achieve the desired effect, has a definite endpoint of correct catheter placement, requires no "test dose," and produces a much more reliable and less spotty block.

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Unfortunately, technical problems have severely limited the usefulness of continuous spinal techniques. Until recently, the standard technique of inserting the spinal catheter through the spinal needle, coupled with the difficulty of manufacturing truly small needles and catheters, has meant large needles and catheters were required. This in turn has resulted in an unacceptably high incidence of post-dural puncture headaches ("PDPH").

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In the mid 1980's, various technical advances fueled renewed interest in spinal anesthesia in general, and in CSA in particular. Improvements in manufacturing ever-smaller conventional (QUINCKE.TM.) spinal needles of 25 gauge, 26 gauge, and even 30 gauge have significantly reduced PDPH incidence. These results have allowed

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for the use of spinal anesthesia in age groups and in procedures which were not previously considered suitable.

At the same time, advances in catheter manufacture have made possible spinal catheters of 28 gauge and 32 gauge which would fit through relatively small spinal needles. Unfortunately, these catheters proved difficult to handle and to make. Moreover, such catheters were expensive, and, more ominously, they were associated with several reports of neurologic damage (*i.e.*, cauda equina syndrome). Many clinicians experimented with these catheters and subsequently abandoned them. These types of catheters were ultimately removed from the market by the Food and Drug Administration ("FDA").

The FDA's decision to recall and ban the marketing of microspinal catheters for CSA in the U.S., and its requirement that any new device for CSA be subjected to an extremely stringent pre-market approval process, have resulted in a freeze on the development of these products, at least in the United States. Nevertheless, the use of such catheters for injecting local anesthetics for the establishing surgical anesthesia is not the only use to which such devices might beneficially be put. In fact, the injection of narcotics, such as FENTANYL.TM., for analgesia during labor would be a very desirable use of such catheters.

Installing a conventional catheter generally requires several cumbersome steps involving threading long, very thin catheters through a spinal needle. Simply threading a catheter into the end of a spinal needle can be so difficult that some manufacturers include a "threading aid" as part of their kit. In short, the conventional spinal catheter threading operation requires considerable time and effort on the part of a clinician. Once threaded, a degree of uncertainty exists for the clinician as to how far to insert the catheter. Also, a risk exists that a piece of the catheter might be sheared off by the needle, if the catheter were to be pulled back during the threading operation. In such cases, bits of catheter could potentially be left behind in the intrathecal space. Furthermore, removing the spinal needle, while holding the catheter in position, can be a challenge. Additionally, attaching a hub/injection adapter to the naked end of the 28 gauge or 32 gauge catheter can be even more of a challenge. Finally, once the adapter is successfully attached, the small lumen of the catheter permits only a slow flow of either

CSF or anesthetic.

A parallel technical development has been the introduction of non-cutting spinal needles, such as the "Pencil Point" type needles, which have been shown to drastically reduce PDPH incidence. Examples of Pencil Point type needles include the Sprotte and
5 Whitacre non-cutting spinal needles. In terms of PDPH incidence, a 22 gauge Sprotte needle seems to be roughly equivalent to a 25 gauge or 26 gauge Quincke needle, while a 24 gauge Sprotte needle or 25 gauge Whitacre needle essentially eliminates the risk of PDPH.

One problem of Sprotte and Whitacre non-cutting spinal needles is that the
10 injection orifice is on the side of the needle. Failures in spinal anesthesia administration have been known to occur when the needle was "half-in, half-out" of the intrathecal space, i.e. the needle was only partially inserted into the intrathecal space. Another problem with Sprotte and Whitacre spinal needles is that the smooth curved tip profile provides no definitive feedback signal or "click" to the clinician when the dura is
15 punctured. This lack of feedback contributes to uncertainty in catheter tip placement for the clinician.

One proposed solution for overcoming the limitations of the conventional catheters mentioned above and a solution which has been approved by the FDA is a flexible spinal needle, described in United States Patent Application 10/694,235, filed
20 October 27, 2003, (U.S. 2005-0090801 A1, published April 28, 2005) the disclosure of which is incorporated by this reference in its entirety herein. Specifically, this particulate flexible spinal needle may be used for CSA while essentially eliminating the risk of PDPH.

25 DISCLOSURE OF THE INVENTION

In order to improve the performance of a flexible needle, a flow element is provided for use in conjunction with the flexible needle. A flow element may be used with flexible needles, including flexible spinal needles, and flexible needle assemblies to prevent, or at least minimize, the extent to which flow occlusion may occur within a
30 flexible needle, particularly when used with a flexible needle for minimizing incidence of post-dural puncture headache. The flow element includes a body having an internal

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flow path for conducting a fluid through a flexible needle and an anti-restriction member. The anti-restriction member includes an elongated body, a proximal end element coupled to the body within the internal flow path, and a distal end element for positioning at least a portion of the elongated body within a flexible needle.

5 In certain embodiments, a parallel flexible spinal needle assembly for minimizing flow occlusion through an internal flow path of a flexible needle, caused by unintended kinking potentially resultant from ligament or muscle layer movements, is also provided.

10 In certain embodiments, a flexible spinal needle assembly, a flexible spinal needle assembly kit, a method for installing a flexible spinal needle assembly, and a process for manufacturing a flow element are provided.

15 Other advantages of the flexible needle and flexible needle assembly, in which a flow element may be used to advantage, are now described. In contrast to a conventional spinal catheter, the instant flexible needle flow element is advantageously used with a flexible needle. The association of the catheter with the flow element provides for simple and straightforward needle insertion without either threading a catheter through a needle or installing an adapter. The installation procedure is similar to intravenous catheter or "single-shot" spinal procedures which are already familiar to clinicians. Placement of the flexible needle over the inserting needle allows for a larger
20 diameter flexible needle to be inserted. The resulting improved diameter flexible needle allows easier and faster flow of either cerebrospinal fluid ("CSF") or medicating agents.

25 Insertion of the flexible needle tip in the intrathecal space with the instant device is more secure than prior devices. The Pencil Point style non-cutting tip of the support needle promotes a low incidence of PDPH. Furthermore, the assembly tip may be shaped to provide a feedback signal when the dura is punctured during the insertion operation. An observation of CSF which is rendered possible with the instant design further assures a clinician that the entire orifice located at the flexible needle tip is positioned in the intrathecal space.

30 The likelihood of neurologic damage is lessened with the shorter flexible needle of the invention. The shorter length makes it less likely that the needle will be wedged against a nerve root. More importantly, the larger bore of the improved flexible needle

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promotes turbulent flow and improved mixing of the fluid to be injected and the CSF. The improved short flexible needle, in association with its hub, removes ambiguity for the clinician as to how far to insert needle in that the needle is inserted to the hub. The flexible needle hub greatly aids fixation of the needle assembly to the patient's skin.

5 Contamination to the entry site during insertion is less likely with the instant invention. Also, kinking of the needle proximate the patient's skin is largely eliminated when a flexible kink sleeve is included in the needle assembly.

The relative ease, simplicity, and safety of the improved inventive device have the potential of beneficially expanding the use of continuous spinal

10 anesthesia/analgesia. Lumbar epidurals could be replaced by using this device. Similarly, most conventional single-shot spinals could be replaced by use of this device, "just-in-case" the procedure goes longer than expected, or the level of the block needs adjustment. A number of situations outside the operating room environment could also benefit from this device, non-exclusively including: acute and chronic pain control with

15 spinal narcotics, labor analgesia, diagnostic taps, and indwelling catheters for continuous peripheral nerve blocks, as well as research efforts. In effect, this device may be used in medical procedures involving needle insertion at the lumbar level of the spine. Versions of the instant device are contemplated to offer improved techniques for the insertion of a wide variety of medical catheters, including arterial lines, major nerve

20 blocks, intraperitoneal catheters, intraventricular (brain) catheters, and intravenous catheters.

The instant device provides an apparatus and method for inserting a flexible spinal needle in a quick, easy, and straightforward manner. The instant flexible spinal needle assembly has an outside diameter which is sized, such that upon withdrawal of

25 the assembly from the subarachnoid space, the dura mater, may substantially reseal the space formerly occupied by the assembly. An assembly typically includes a support needle, a flexible needle, slidably mounted on the support needle, and a central stylet slidably inserted within the support needle. The inserted tip end of the flexible needle assembly is advantageously configured to produce a feedback signal during the insertion

30 process to indicate dural puncture.

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A support needle may have a piercing point on a first end and a central hub at a second end. The piercing point protrudes from a front, distal, inserted, or tip, end of the flexible spinal needle assembly. The piercing point is adapted to penetrate, substantially without cutting, and helps to form a puncture hole through the dura mater which substantially reseals itself automatically subsequent to a retraction of the flexible needle.

A second end of the central stylet generally may have a locking hub. The locking hub may carry a first attachment structure for connecting with corresponding structure carried by the central stylet.

The front end of the support needle may be configured cooperatively to form a structural interference with a distal end of a flexible needle. This structural interference resists a relative motion between the piercing point of the support needle and the distal end of the flexible needle during the insertion of the flexible needle into a patient. A rear end of the support needle may carry a support hub having second attachment structure for removably connecting the support needle to the central hub of the central stylet. The first and second attachment structures may be structured to form a removable connection, such as a LUER-LOCK.TM. type connection. The support hub may be advantageously made from a transparent material to permit the clinician to observe fluid flow through the support hub.

A flexible needle may be viewed as a flexible conduit having distal and proximal ends. Preferred flexible needles have sufficient transverse flexibility to accommodate a patient's torso bending movement. This flexibility operates to reduce a patient's awareness of the presence of the inserted device. Flexible needles typically are made from medical grade plastic materials. For example, polyester shrink tube or similar materials may be used. The distal end of a flexible needle may be reinforced, in some instances, in order to resist a displacement or peel-back of the distal end from the front end of a support needle.

The portion of the assembly which transitions from the proximal flexible needle hub to the flexible needle body may be reinforced by a kink sleeve segment. The kink sleeve segment may be constructed of a firm, yet flexible material, such as nylon or other polymers. The kink sleeve is intended to cushion the effects of forces applied to the assembly over the area of transition from the hub to the flexible needle body during

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instances of bending that may occur after the flexible needle is inserted and the support needle is removed. For example, once the flexible needle is inserted, the hub may be bent over and taped to the patient's skin, often at an angle of approximately 90 degrees.

Needle hubs are typically configured for fluid flow attachment to medical fluid transfer equipment. For example, needle hubs may be configured to form LUER-LOCK.TM. type connections with such equipment. It may be preferred to form the needle hub for substantially unobtrusive attachment to a patient's skin by way of an intermediary adhesive element. Alternatively, the hub may be designed to lay flush against the patient's skin with a connection positioned parallel thereto thereby avoiding a need for bending the flexible needle.

A flexible needle assembly may be installed using a method as follows: providing a flexible needle assembly as disclosed herein;

using a conventional spinal needle technique to prepare the skin of a patient at an injection site, applying local anesthetic, piercing the patient's skin and subcutaneous fascia, and inserting a piercing point tip of the flexible spinal needle assembly;

removing the central stylet subsequent to receiving a feedback signal that a puncture of the dura mater has occurred;

checking for the presence of CSF at the support hub; if no CSF is observed, further inserting the assembly until the tip is within the intrathecal space; or if CSF is observed, unlocking the support hub and the flexible needle hub, and while holding the support needle stationary, advancing the flexible needle until the flexible needle hub contacts the patient's skin;

removing the support needle and checking for the presence of CSF at the flexible needle hub;

positioning and connecting a flow element into an internal flow path of the flexible needle to substantially reduce flow occlusion through the internal flow path caused by kinking;

connecting a medical fluid transfer apparatus to an attachment hub of the flow element; and finally,

securing the flexible needle hub to the skin..

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded plan assembly view of a flexible needle assembly.

FIG. 2 is an exploded plan assembly view of a second embodiment of a flexible
5 needle assembly.

FIG. 3 shows a partial cross-sectional view of the flexible needle shown in FIG.
1.

FIG. 4 shows a detail view of a distal end portion of the flexible needle assembly
tip shown in FIG. 1 when assembled.

10 FIG. 5 is a plan view of a flow element of the flexible needle assembly shown in
FIG. 2.

FIG. 6 shows an exploded view the flow element as indicated by reference in
FIG. 5.

FIG. 7 shows a cross-sectional view taken along section line 7-7 in FIG. 5.

15 FIG. 8 is a side assembled view of the flexible needle assembly shown in FIG. 2.

FIG. 9 representatively shows a portion of the flexible needle assembly shown in
FIG. 8 being kinked in ligament layers.

FIG. 10 shows a cross-sectional view of the flexible needle assembly taken
along section line 10-10 in FIG. 9.

20 FIG. 11 illustrates a cross-sectional view of a conventional flexible needle being
partially occluded when bent in ligament layers.

FIG. 12 illustrates a cross-sectional view of a conventional flexible needle being
fully occluded when kinked in ligament layers.

FIG. 13 shows a cross-sectional view of another flexible needle assembly.

25 FIG. 14 shows a cross-sectional view of a further flexible needle assembly.

FIG. 15 shows a cross-sectional view of yet another flexible needle assembly.

FIG. 16 shows a cross-sectional view of a flow element.

FIG. 17 shows a cross-sectional view of a flow element.

FIG. 18 shows a cross-sectional view of a flow element.

30 FIG. 19 is a side view of a flexible spinal needle assembly.

MODE(S) FOR CARRYING OUT THE INVENTION

The illustrations presented herein are, in some instances, not actual views of any particular flow element, flexible needle assembly or other feature of a flexible spinal needle assembly, but are merely idealized representation that are employed to describe the invention. Additionally, elements common between figures may retain the same numerical designation.

Generally, the flow element may be advantageously used with an integrated spinal needle or flexible needle assembly 10 (much like an intravenous needle and catheter mounted therein) as shown in FIG. 1, with the flexible needle 15 being releasably mounted on the outside of a support needle 19. The flexible needle 15 is configured for uses with embodiments of the invention as will be further described below. Flexible needle 15, being configured for placement on the outside of the support needle 19, provides a number of advantages which are first described hereafter, prior to turning to the embodiments of the invention. First, this design makes insertion significantly easier by eliminating the separate steps of catheter threading, insertion and hub/adaptor attachment. A single “stick” or insertion is all that is required; once the needle is inserted into position, the flexible conduit is likewise in position for purposes of infusing fluid. Since the flexible needle 15 is larger for a given needle size, its flow and handling characteristics will be much improved, and it is easier and cheaper to manufacture. Advantageously, embodiments of the invention may provide for a flow element 50 that may be introduced into the flexible needle 15 to minimize the effects of kinking by substantially preventing total flow occlusion of fluid through the flexible needle, thereby ensuring a minimal amount of fluid flow through the needle as shown in FIG. 2.

Shown in FIG. 1 is an exploded plan assembly view of a flexible needle assembly 10 which is usable in accordance with an embodiment of the invention. The flexible needle assembly 10 consists of three components: a central stylet 17, a hollow support needle 19, and a flexible needle 15. The overall dimensions of the flexible needle 15 and representatively the flexible needle assembly are generally represented in length, and may be similar to a conventional spinal needle in gauge size ranging from

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about 22 gauge to about 25 gauge in size, but as illustrated the flexible needle 15 is shown as being about 23 gauge cannula in size.

The innermost component of the assembly is configured as a solid central stylet 17. When inserted in the support needle 19 (discussed in detail further herein), the central stylet 17 prevents the entry of extraneous tissue or other material into the support
5 needle opening 28 during insertion of the assembly into the patient. The central stylet may also serve as a “stiffening” portion of the assembly providing extra support and stiffness to the entire assembly. The hub 25 of the central stylet 17 is configured to be positioned outermost, or located at an extreme proximal end 26 of assembly 10. This
10 positioning facilitates the removal or disengagement of the central stylet 17 from the assembly 10. In most instances the stylet is the first component which is disengaged from the assembly 10 subsequent to the insertion of the assembly into the patient. An attachment structure, such as resilient tab 32, may be located on the hub 25 for retaining the central stylet 17 in the support needle 19. The tab 32 may interact with a
15 corresponding attachment structure on the hub 35 of the support needle 19.

The next layer of the assembly is a removable hollow support needle 19 to support and allow insertion of the flexible needle 15 into a subject. This support needle 19 closely resembles a conventional spinal needle. The tip 27 of support
20 needle 19 may have a pencil-point formation to allow penetration of tissue substantially without cutting. As discussed previously herein, this aids in forming a puncture hole through the dura mater which automatically may substantially reseal subsequent to retraction. An opening 28 is located near the tip 27 to allow cerebral spinal fluid “CSF” or other fluids to flow through the support needle 19 from the opening 28 to the hub 35. It will be appreciated that where desired, suitable treatment solutions may be injected
25 through the support needle 19, to enter a patient’s tissue through the opening 28.

The hub 35 of the support needle 19 may beneficially be made of clear plastic to permit the clinician to view CSF return when the central stylet 17 has been removed. Of course, any CSF present will visibly flow from the distal end 33 of support needle 19 subsequent to removal of the central stylet 17. Optional use of clear plastic or a
30 transparent fluid observation window in the support hub 35 can provide an additional convenience, and minimize loss of CSF.

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The central stylet 17 may be attachable to the support needle 19, as illustrated in FIG. 1. The central hub 25 typically carries an attachment structure, such as tab 32, to interface in a structural interference with an attachment structure 34 carried by support hub 35. As illustrated, tab 32 and attachment structure 34 cooperatively form a slidably engageable joint. Alternative releasable retaining joint configurations, including rotatable attachments such as LUER-LOCK.TM. type joints, may also be used.

The outermost layer or portion of the assembly 10 is the flexible needle 15 itself. As previously described the flexible needle 15 is approximately 23 gauge in size and about the length of a conventional spinal needle, although the adoption of different diameters and lengths for use with different procedures is within the scope of the invention. Conventional plastic catheter material may be used in the construction of needle 15. The flexible needle material may be reinforced with a flat ribbon internal spring 45 (shown in FIG. 4), an internal or external wire wrap, or other reinforcing structure. Alternative materials, and various materials in combination, also may be used to construct a flexible needle 15. Suitable flexible needle material produces a flexible needle 15 which is fairly stiff and has a sufficiently high tensile strength to maintain structural integrity during insertion, during residency in the body, and during retraction from the patient. A flexible needle 15 desirably possesses sufficient transverse flexibility to deform and accommodate patient motion in order to reduce irritation to the patient resulting from the presence of a foreign body.

A slippery nonstick surface is generally provided to ease insertion and removal of the flexible needle 15. The tip 29 of flexible needle 15 may be tapered into a curve to blend smoothly into the edge of support needle 19 (*see*, FIGS. 4 & 19). The degree of this curved taper may be governed by a tradeoff between the decreased resistance to insertion of an extreme taper versus the fragility and tendency to peelback of a very thin leading edge. A preferred taper provides ease of insertion, a feedback signal to indicate entry of flexible needle 15 through the dura, and sufficient tensile strength to prevent peelback. The feedback signal may be described as a distinct "click" or a discernible change in the required insertion force. The "click" may be a sonic event, or may be tactilely perceptible through the clinician's fingers in contact with the assembly.

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Flexible needle tips 29, having shapes in addition to those illustrated in FIGS. 1 and 4, are within contemplation. For example, manufacturing or material requirements may influence the shape of a tip 29. An alternative flexible needle may include a reinforcing wire of fine gauge. Such a wire may be embedded into the material forming the sealing wall of flexible needle 15 to reinforce against peelback. The wire may also be spiraled along the length of the flexible needle to provide additional strength to resist collapse, kinking, or breakage of a flexible needle 15. Alternatively, a flat spring ribbon 45 may be used to provide reinforcement.

The flexible needle hub 39 typically includes a LUER-LOCK.TM. type connector, or other attachment structure, for easy and secure connection with common infusion tubing, injection ports, or syringes, and other medical fluid transfer apparatus. Since the flexible needle 15 may be inserted all the way to the hub 39, a flat, circular flange, or other ergonomically shaped structure, may be provided on the surface of the hub which rests against the patient's skin to facilitate easy tape fixation. Fixation to the patient's skin may be accomplished with a slotted circular foam tape. Of course, other tapes or adhesive systems may also be used. A quantity of suitable adhesive or tape could be included in a prepackaged flexible spinal needle assembly kit.

It is desirable to prevent inadvertent premature removal of the support needle 19 from the flexible needle 15. In the embodiment depicted in FIG. 1, support hub 35 is configured to threadedly receive the threaded structure 37, which is located on the flexible needle hub 39, and form a releaseable locked connection with the structure 37 upon a rotation of the structure 37 relative to the support hub 35 or vice-versa. Such a positive connection may be desirable and may form a LUER-LOCK.TM. or other rotatable-type joint. Other such interlocking or even alternative retaining structure may also be used. For example, a secure friction fit attachment between support needle 19 and flexible needle 15 is within contemplation in the practice of this invention, as is a structural interference fit of attachment structures similar to that shown in connection with tab 32 on the central stylet 17.

FIG. 3 illustrates a partial cross-sectional view of the flexible needle shown in FIG. 1. The flexible needle 15 may include a flexible kink sleeve 18. Kink sleeve 18 covers a portion of the proximal surface of the flexible needle 15 to protect the area

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covered against kinking and damage during bending. Desirably, the kink sleeve 18 will begin at the base of the flexible needle 15 inside the hub 39 (as depicted in FIG. 3) to provide maximum protection. Alternate embodiments, where kink sleeve begins at a location spacedly removed from the end of the flexible needle inside the hub 39, or at the end of the hub 39 are within the scope of the invention. Kink sleeve 18 may extend along the length of the flexible needle 15 to a length or distance appropriate for the planned use of the flexible needle. Typically, kink sleeve 18 will extend to a length sufficient to prevent kinking of the flexible needle at the skin of the patient or within the skin and fascia of the patient. Kink sleeve 18 may be constructed of any suitable flexible material that is medically acceptable, including polymers such as nylon.

When flexible needle 15 is fully inserted, a portion of the kink sleeve 18 may reside within the skin and fascia of the patient. The hub 39 may then be bent over and taped to the skin, if desired. The kink sleeve 18 acts to protect the flexible needle 15 during this bending process, which may bend the flexible needle 15 at an angle of about 90 degrees or more. The kink sleeve 18 absorbs the force of the bend and maintains the flexible needle 15 in a position allowing fluid flow therethrough. Kinking of the flexible needle 15 is thus minimized, and may be largely prevented. The kink sleeve 18 may be impregnated, coated, or otherwise treated with a biocompatible infection resistant substance to prevent adverse tissue reaction or infection at the flexible spinal needle entry site.

Flexible needles 15 may be made from suitable medical grade, plastic type materials. For example, polyester shrink tubing may be employed in one embodiment of the device, although it will be appreciated that any suitable material, including other polymers, may be used. Flexible needles 15 may be composed of a single material, or may be a composite of two or more materials to provide the desired flexible needle handling characteristics. Fine gauge wire, such as stainless steel wire, or a flat internal ribbon spring 45 (shown in FIG. 4), may be incorporated into a flexible needle sealable wall to improve resistance to peelback and to further support the structural integrity of the flexible needle. The distal ends may alternatively be reinforced with metal bands. Hubs 25, 35 and 39 are typically also made from medical grade plastic type materials.

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The central stylet 17 and support needle 19 are typically made from a medically acceptable metal, such as stainless steel or titanium.

The design of this device makes the placement of a spinal flexible needle 15 quick, easy, and straightforward. It should be so easy, in fact, that most clinicians may choose to use this device for every spinal procedure they perform. The initial steps of skin preparation, local anesthetic infiltration, and needle insertion are identical to those now used with conventional spinal needles. As the flexible needle assembly 10 is being inserted and the clinician feels the slight "click" upon dural puncture, he or she removes the central stylet 17. If the insertion has been successful, CSF will promptly appear at the hub 35 of the support needle 19. If the dura has not been penetrated, the entire assembly 10 may continue to be advanced until dural puncture is achieved. If desired, the central stylet 17 may be reinserted prior to continued advancement in order to prevent tissue from entering the opening 28.

Once CSF is observed at the hub 35 of the support needle 19, the clinician can have confidence that the tip 29 of the flexible needle 15 is within the intrathecal space. If desirable for the procedure, the clinician may continue to advance the hollow support needle/flexible needle 19/15 of the assembly 10 another centimeter or so. At this point, the hub 35 of the hollow needle 19 is typically rotated or twisted to unlock it from engagement with the flexible needle hub 39. While holding the hollow needle 19 stationary, the clinician further advances the flexible needle 15 into the patient until the hub 39 contacts the patient's skin. For embodiments including a kink sleeve 18, this advancement may insert, or further insert, the kink sleeve 18 within the patient's skin.

At this point, the hollow support needle 19 may be removed, and the appearance of CSF at the flexible needle hub 39 will confirm the correct placement of the flexible needle 15. The desired injection port, tubing, or other medical fluid transfer apparatus, may then be attached to the flexible needle hub 39 such as by way of attachment structure 37. Where necessary, the flexible needle 15 may be bent and taped to the patient's skin before or after the attachment of the corresponding apparatus, if required.

Where included, kink sleeve 18 protects the flexible needle 15 from kinking and incurring damage at the bend. A piece of slotted, circular foam tape (which might also be treated with an antimicrobial substance) may also be applied to secure the hub 39 to

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the skin, thereby preventing a dislodgement of the flexible needle 15, and furthermore providing a cushion to the patient to reduce potential irritation from the hub 39.

The flexible needle 15 may then be left in place for as long as clinically necessary and, assuming adequate tensile strength, may be easily and safely removed
5 when appropriate. At the time of removal, since the non-cutting point 22 of the support needle 19 substantially eliminates laceration of any of the fibers in the dural membrane, the mesh-like fibers may relax to their original position, thus automatically closing or resealing the dural puncture. As a result the incidence of PDPH is expected to be in agreement with that experienced with Sprotte and Whitacre needles, despite the luxury
10 or provision of a reasonably large flexible needle 15 in a device usable to advantage with the instant invention.

FIG. 2 is an exploded plan assembly view of a flexible needle assembly 100 in accordance with a further embodiment of the invention. The flexible needle assembly 100 comprises a flexible needle 15 as previously described and a flow element
15 50, and may further comprise a central stylet 17, and a hollow support needle 19. FIG. 8 shows a side assembled view of the flexible needle assembly 100 shown in FIG. 2. The overall dimensions of the flexible needle 15 and the flow element 50 are generally represented in length as indicated by reference line R_L, and may be similar to a conventional spinal needle in gauge size ranging from about 22 gauge to about 25 gauge
20 in size. As illustrated the flexible needle 15 is shown as being approximately 23 gauge cannula in size. The flow element 50 is dimensioned to be sufficiently small so as to be positioned within an inner flow path 72 (shown in FIG. 8) defined within the flexible needle 15.

FIG. 5 is a plan view of the flow element 50 of the flexible needle assembly 100
25 shown in FIG. 2. The flow element 50 is advantageously used with the flexible needle 15 to further prevent kinking of the flexible needle 15 or from substantially occluding fluid flow through the needle when the needle is inserted through muscle or ligament layers 90 of a patient as illustrated in FIG. 9. FIG. 10 illustrates a cross-sectional view of the flexible needle assembly taken along section line 10-10 of FIG. 9 wherein the
30 flexible needle 15 is kinked and an anti-restriction member 56 of the flow element 50 prevents fluid occlusion within the inner flow path 72.

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FIG. 11 illustrates a cross-sectional view of a conventional flexible needle 15 being partially occluded when bent in ligament layers and FIG. 12 illustrates a cross-sectional view of a conventional flexible needle 15 being fully occluded when kinked in ligament layers.

5 Returning to FIG. 5, The flow element 50 includes a body 52 having an internal flow path 54 for conducting a fluid through the flexible needle 15 and an anti-restriction member 56. The anti-restriction member 56 includes elongated bodies 58, a proximal end 60 coupled to the body 52 within the internal flow path 54, and a distal end 62 for disposing at least a portion of the elongated body 58 within the flexible needle 15.

10 Advantageously, the elongated body 58 will help to maintain a minimal amount of fluid flow through the flexible needle 15 should kinking thereof occur. FIG. 9 representatively shows a portion of the flexible needle assembly 100 shown in FIG. 8 being kinked in ligament layer 90 as mentioned above.

The body 52 may be made from any suitable material, and in this embodiment is

15 made from a medical grade plastic. The anti-restriction member 56 is made from a medical grade stainless steel and may be made from any other suitable material. The flow element 50 may be manufactured by known methods, such as injection molding, by locating the anti-restriction member 56 into a mold and then forming the body 52 about member 56. Other methods may be utilized to manufacture the flow element 50, such

20 as by forming the body 52 using conventional techniques and then securing the anti-restriction member 56 to the body 52, for example, with glue.

The body 52 may include a cylindrical outer surface 53 extending substantially between a first end 55 and a second end 57, wherein a portion of the cylindrical outer surface 53 is configured for sealing attachment to the attach structure 39 of the flexible

25 needle 15. A flexible conduit 64 may be coupled to the first end 55 of the body 52 to supply fluid thereto or for connection to a machine configured for delivering fluids thereto. A support hub 66 may be coupled to the body 52, the support hub 66 having a first attach structure 68 configured to removably attach to the attach structure 37 of the flexible needle to allow at least a portion of the elongated body 58 to be disposed

30 therein. Optionally, the first attach structure 68 may comprise a LUER-LOCK.TM. type

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of connector or any other suitable connector type for attaching to the flexible needle 15.

FIG. 7 shows a cross-sectional view of the anti-restriction member 56 taken along section line 7-7 in FIG. 5. As shown, the anti-restriction member 56 may include two elongated bodies 58 in this embodiment. As shown in FIG. 6, the two elongated bodies 58 may include a twisted pair of wires. Optionally, the twisted wire pair may be secured on one end with a weld bead 70. Manufacturing the anti-restriction member 56 may include receiving two wires and positioning them one on the other relative to their axial lengths, optionally twisting them and further securing them together with a weld bead, so as to leave one end prepped for securing to, or forming with, the body 52 and the other end for positioning in a flexible needle as herein described. It is to be recognized that the anti-restriction member 56 may include one or three or more elongated bodies other than the two elongated bodies 58 as illustrated by the twisted wire pair. For example: FIG. 13 shows a flexible needle 15 having a single elongated body 158 of an anti-restriction member 156 positioned therein; FIG. 14 shows a flexible needle 15 having three elongated bodies 258 of an anti-restriction member 256 disposed therein; and FIG. 15 shows a flexible needle 15 having four elongated bodies 358 of an anti-restriction member 356 disposed therein. Each of the illustrated embodiments provides a different amount of minimal fluid occlusion should the flexible needle 15 be kinked when used.

It is to be recognized that each elongated body 58 of the anti-restriction member 56 while shown as a single uniform structure, may comprises two or more wires or elements banded, twisted or coupled together to form the unitary elongated body 58. However, in this embodiment the anti-restriction member 56 comprises six wires (not shown) for each of the two elongated bodies 58 shown in FIG.10.

Optionally, each elongated body 58 of the anti-restriction member 56 may be configured with a cross-sectional shape of a circle as shown in FIG 10, an ellipse (not shown), a diamond as shown in FIG. 17, a jack as shown in FIG. 16, a square (not shown), a triangle (not shown), a sigmoid as shown in FIG. 18 or any other suitable cross-sectional shape for advantageously preventing and minimizing flow occlusion through a flexible spinal needle assembly 100.

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Advantageously, the anti-restriction member 56 effectively maintains an open channel within the inner flow path 72 of the flexible needle 15 upon a bending or kinking of the needle 15.

5 The flow element 50 may be configured such that the distal end 62 of the elongated body 58 protrudes partially from a flexible distal end of the flexible needle 15 to allow the fluid to be dispersed more effectively from the cannula of the flexible needle 15, or may be configured to have a length which is either greater or smaller than that illustrated.

FIG. 19 is a perspective view of a flexible spinal needle 215. The flexible spinal
10 needle 215 may be used with a flow element 50 for minimizing flow occlusion through an internal flow path thereof by unintended kinking that is potentially caused by ligament or muscle layer movements when inserted into dura mater and into the intrathecal space of a subject. The flexible spinal needle 215 includes an internal flow path (not shown) advantageously for receiving a flow element 50 for coupling with the
15 flexible needle 215 and disposed through a substantial portion of the internal flow path.

The flexible needle includes an exterior diameter such that withdrawal of the flexible needle from the dura mater, permits the dura mater to substantially reseal a space formerly occupied by the flexible needle. A tip and a flexible needle body of the flexible needle are of a substantial elongated extent such that they can be further
20 extended into the dura mater upon extraction of a support needle coupled therewithin before exposing the flow element 50 therewithin. Optionally, the distal end or tip 227 of the flexible spinal needle 215 may include a curved portion 230 to facilitate further insertion into an intrathecal space of a patient upon removal of a support needle 19 that naturally strengthens while supporting the flexible material characteristics of the
25 flexible spinal needle 215. The curved portion 230 may be manufactured by forming the material in the desired shape or otherwise providing material strain or strain relief strategically located in a portion of the material forming the cannula of the flexible spinal needle 215. The curved portion 230 may be formed using manufacturing methods understood by a person of skill in the art.

30 In still other embodiments of the invention, a flexible spinal needle assembly kit is provided. The flexible spinal needle assembly kit includes a flow element,

configured for minimizing flow occlusion through a flow path upon its insertion into a flexible needle and a flexible needle, having a flow path and configured for receiving a flow element or a support needle within the flow path. The flexible spinal needle assembly kit may further include a support needle configured for insertion into the flexible needle to minimize the transverse flexibility of the flexible needle to enable
5 insertion of the support needle and coaxially supported flexible needle through dura mater and into the spine of a patient. The flexible spinal needle assembly kit may also include a central stylet configured for removable insertion into the support needle to prevent entry of matter through an opening proximate a distal end of the support needle
10 when inserted into a patient.

Optionally, the flexible spinal needle assembly kit may include the support needle and the flexible needle in a pre-assembled form allowing insertion of the pre-assembly into a patient and facilitating a removal of the support needle and subsequent insertion of the flow element into the flexible needle. Likewise, the central stylet, the
15 support needle and the flexible needle may be pre-assembled for facilitating insertion of the pre-assembly into a patient and further to facilitate removal of the support needle and central stylet and subsequent insertion of the flow element into the flexible needle.

A method for installing a flexible spinal needle assembly in accordance with embodiments of the invention may include: inserting a distal end of a flexible spinal
20 needle assembly provided through dura mater and into an intrathecal space of a patient, the spinal needle assembly including: a support needle with a non-cutting piercing point at the distal end and a hollow bore; a flexible needle with a tip at the distal end and slidably mounted on and supported by the support needle to expose the piercing point slightly extending beyond the tip in the distal end thereof, the flexible needle having an
25 outside diameter sufficiently small so that upon insertion of the flexible spinal needle assembly and withdrawal of the support needle from the flexible needle permits the dura mater substantially to seal against the outside diameter of the flexible needle; removing the support needle from within the flexible needle while maintaining the tip of the flexible needle within the intrathecal space to expose an inner flow path; and thereafter,
30 connecting a flow element to the flexible needle positioning an anti-restriction member

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of the flow element into the inner flow path of the flexible needle to substantially prevent fluid occlusion caused by bending or kinking of the flexible needle.

The method for installing a flexible spinal needle assembly may further include, prior to removing the support needle from within the flexible needle, verifying a presence of cerebrospinal fluid in a proximal end of the flexible spinal needle assembly; if no cerebrospinal fluid is observed, further inserting the distal end of the flexible spinal needle assembly through the dura mater until the tip is at least positioned in the intrathecal space; and thereafter removing the support needle from within the flexible needle upon observing the presence of cerebrospinal fluid within the flexible spinal needle assembly.

Optionally, inserting the distal end of the flexible spinal needle assembly through dura mater and into the intrathecal space of the patient wherein the outside diameter of the flexible needle is sufficiently small so that upon withdrawal of the flexible needle from the dura mater, subsequent to insertion of the flexible spinal needle assembly therethrough, the dura mater may substantially to reseal a space formerly occupied by the flexible needle.

The method for installing a flexible spinal needle assembly may include utilizing a central stylet slidably mounted in the support needle to prevent the entry of matter through an opening in the distal end of the support needle during an insertion procedure, and further including prior to removing the support needle from within the flexible needle, checking for cerebrospinal fluid at a proximate end of the spinal needle assembly; if no cerebrospinal fluid is observed, replacing the central stylet and further inserting the spinal needle assembly until the tip is in the intrathecal space; and once cerebrospinal fluid is observed, then removing the central stylet.

The method for installing a flexible spinal needle assembly may also include utilizing a central stylet slidably mounted in the support needle to prevent the entry of matter through an opening in the distal end of the support needle during an insertion procedure, and further including prior to removing the support needle from within the flexible needle, checking for cerebrospinal fluid at a proximate end of the spinal needle assembly; if no cerebrospinal fluid is observed, replacing the central stylet and further

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inserting the spinal needle assembly until the tip is in the intrathecal space; and once cerebrospinal fluid is observed, then removing the support needle and the central stylet.

Optionally, removing the support needle from within the flexible needle includes advancing the flexible needle into the intrathecal space until a proximate end hub of the flexible needle contacts the patient.

The method for installing a flexible spinal needle assembly may further include subsequent to removing the support needle from within the flexible needle, checking for the presence of cerebrospinal fluid at a flexible needle hub on a proximate end of the flexible needle prior to positioning the anti-restriction member of the flow element into the inner flow path of the flexible needle.

The method for installing a flexible spinal needle assembly may optionally include subsequent to removing the support needle from within the flexible needle and after positioning the anti-restriction member of the flow element into the inner flow path of the flexible needle and connecting the flow element to the flexible needle, connecting medical fluid transfer apparatus to the flow element for supplying fluid into the inner flow path; and securing the flexible needle hub to the patient.

The method for installing a flexible spinal needle assembly may still further include, prior to inserting the distal end of the flexible spinal needle assembly through dura mater and into the intrathecal space of the patient, preparing the skin of a patient at an injection site; applying local anesthetic at the injection site; and inserting the distal end of the flexible spinal needle assembly into the prepared injection site.

The method for installing a flexible spinal needle assembly may include checking for cerebrospinal fluid and removing the central stylet subsequent to receiving a feedback signal that puncture of the dura mater has occurred.

Lastly, the method for installing a flexible spinal needle assembly may include utilizing a flow element including: a body having an internal flow path for conducting a fluid through the flexible needle; and an anti-restriction member having an elongated body, a proximal end coupled to the body within the internal flow path, and a distal end to facilitate positioning at least a portion of the elongated body within the inner flow path of the flexible needle.

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After having been apprised of the disclosure hereof, one of ordinary skill in the art would be able to make and use the invention.

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CLAIMS

What is claimed is:

- 5 1. A flow element for use with flexible needles, the flow element comprising:
 a body having an internal flow path for conducting a fluid through a flexible
 needle; and
 an anti-restriction member having an elongated body, a proximal end coupled to
10 the body within the internal flow path, and a distal end for disposing at least a portion of
 the elongated body within a flexible needle.
2. The flow element of claim 1, wherein the body is made from a medical
 grade plastic, the anti-restriction member is made from a medical grade stainless steel
15 and the body includes a cylindrical outer surface extending substantially between a first
 end and a second end, wherein a portion of the cylindrical outer surface is configured
 for sealing attachment to an attachment structure of a flexible needle.
3. The flow element of claim 2, further comprising a conduit coupled to the
20 first end of the body and a support hub coupled to the body, the support hub having a
 first attach structure configured to removably attach to an attach structure of a flexible
 needle while disposing at least a portion of the elongated body therein, the first attach
 structure comprises a luer lock type connector.
- 25 4. The flow element of claim 1, wherein the elongated body of the
 anti-restriction member comprises two or more wires.
5. The flow element of claim 4, wherein the elongated body of the
 anti-restriction member comprises six wires.

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6. The flow element of claim 1, wherein the anti-restriction member comprises a plurality of elongated bodies.

7. The flow element of claim 6, wherein the plurality of elongated bodies comprises a twisted wire pair, and each elongated body of the twisted wire pair comprises a plurality of wires.

8. The flow element of claim 6, wherein the plurality of elongated bodies are secured distally with a weld bead.

10

9. The flow element of claim 1, further comprising a flexible needle removably attached to the body disposing at least a portion of the elongated body of the anti-restriction member within an inner bore of the flexible needle for preventing total occlusion of the internal flow path resulting from kinking of the flexible needle caused by ligament or muscle layer movement in a subject.

15

10. The flow element of claim 9, wherein the distal end of the elongated body protrudes from a flexible distal end of the flexible needle, the flexible needle is configured having an outside diameter sized so that withdrawal of the flexible needle from dura mater of a spine, subsequent to insertion of the flexible needle through the dura mater, permits the dura mater substantially to reseal a space formerly occupied by the flexible needle, the elongated body of the anti-restriction member is configured for substantially preventing partial occlusion of the internal flow path, and the flexible needle is configured for slidably mounted on a portion of a support needle such that a first end of the support needle protrudes from the flexible needle exposing a non-cutting piercing point for allowing the flexible needle and support needle to be inserted through the dura mater and into the intrathecal space of a subject and upon removal of the support needle is configured for disposing a portion of the anti-restriction member within the flexible needle.

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11. The flow element of claim 10, wherein a flexible needle body of the flexible needle is of such substantial axial extent to be further extendable into the dura mater upon extraction of a support needle, and the body comprises a support hub having a first attach structure, and a proximal end of the flexible needle carries a flexible needle
5 hub having a second attach structure configured to removably attach to the first attach structure carried by the support hub.

12. The flow element of claim 14, wherein the flexible needle comprises a cannula formed from a first material and radially reinforced over an extent toward a
10 distal portion of the inner bore by a second material comprising a stainless steel ribbon spring and further comprises a kink sleeve disposed on a portion of a flexible needle hub and over a portion of a cannula of the flexible needle.

13. A flexible spinal needle assembly for minimizing flow occlusion through
15 an internal flow path of a flexible needle by unintended kinking, potentially caused by ligament or muscle layer movements, when inserted into dura mater and into the intrathecal space of a subject, the flexible spinal needle assembly comprising:

the flexible needle having the internal flow path; and

a flow element coupled to the flexible needle and disposed through a substantial
20 portion of the internal flow path.

14. The flexible spinal needle assembly of claim 13, wherein the flexible needle has an exterior diameter such that withdrawal of the flexible needle from the dura mater, subsequent to insertion of the flexible needle assembly therethrough,
25 permits the dura mater substantially to reseal a space formerly occupied by the flexible needle, and a tip and a flexible needle body of the flexible needle are of substantial elongated extent to be further extendable into the dura mater upon extraction of a support needle coupled therewithin before exposing the flow element therewithin, and wherein the flow element is configured for attachment to medical fluid transfer
30 equipment having structure to form a luer lock type connection.

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15. The flexible spinal needle assembly of claim 25, wherein the flow element comprises:

a body comprising the internal flow path; and

5 a member having a plurality of elongated bodies, a proximal end coupled to the body within the internal flow path, and a distal end for disposing at least a portion of the plurality of elongated bodies within the flexible needle.

16. A flexible spinal needle assembly comprising:

10 a flexible needle having a flexible needle body comprising an elongated hollow tube and a flow path; and

a flow element disposed in the flow path and configured for minimizing flow occlusion through a flow path.

17. The flexible spinal needle assembly of claim 16 comprises a flexible spinal needle assembly kit comprising a prepackaged and sterilized assembly comprising the flow element and the flexible needle.

18. The flexible spinal needle assembly kit of claim 17, further comprising a support needle configured for insertion into the flexible needle and to minimize the transverse flexibility of the flexible needle to enable insertion of the support needle and coaxially supported flexible needle through dura mater and into a spin of a subject, and a central stylet configured for removable insertion into the support needle to prevent entry of matter through an opening proximate a distal end of the support needle when inserted into a subject, wherein the support needle and the flexible needle are pre-assembled allowing insertion of the pre-assembly into a patient facilitating removal of the support needle and subsequent insertion of the flow element into the flexible needle.

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19. A method for installing a flexible spinal needle assembly, the method comprising:

inserting a distal end of a flexible spinal needle assembly provided through dura mater and into an intrathecal space of a subject, the spinal needle assembly comprising:

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a support needle with a non-cutting piercing point at the distal end and a hollow bore; a flexible needle with a tip at the distal end and slidably mounted on and supported by the support needle to expose the piercing point slightly extending beyond the tip in the distal end thereof, the flexible needle having an outside diameter sufficiently small so that upon insertion of the flexible spinal needle assembly and withdrawal of the support needle from the flexible needle permits the dura mater substantially to seal against the outside diameter of the flexible needle;

10

removing the support needle from within the flexible needle while maintaining the tip of the flexible needle within the intrathecal space to expose an inner flow path; and

15

thereafter, connecting a flow element to the flexible needle disposing an anti-restriction member of the flow element into the inner flow path of the flexible needle to substantially prevent fluid occlusion caused by bending or kinking of the flexible needle.

20

20. The method of claim 19, further comprising, prior to removing the support needle from within the flexible needle, verifying presence of cerebrospinal fluid in a proximal end of the flexible spinal needle assembly; if no cerebrospinal fluid is observed, further inserting the distal end of the flexible spinal needle assembly through dura mater until the tip is at least in the intrathecal space; and thereafter removing the support needle from within the flexible needle upon observing cerebrospinal fluid presence within the flexible spinal needle assembly, wherein inserting the distal end of the flexible spinal needle assembly through dura mater and into the intrathecal space of the subject comprises the outside diameter of the flexible needle being sufficiently small so that upon withdrawal of the flexible needle from dura mater, subsequent to insertion

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of the flexible spinal needle assembly therethrough, permits the dura mater substantially to reseal a space formerly occupied by the flexible needle, and the spinal needle assembly further comprises a central stylet slidably mounted in the support needle to prevent the entry of matter through an opening in the distal end of the support needle during inserting, and further comprising prior to removing the support needle from within the flexible needle checking for cerebrospinal fluid at a proximate end of the spinal needle assembly; if no cerebrospinal fluid is observed, replacing the central stylet and further inserting the spinal needle assembly until the tip is in the intrathecal space; and once cerebrospinal fluid is observed, then removing.

10

21. The method of claim 19, further comprising subsequent to removing the support needle from within the flexible needle checking for the presence of cerebrospinal fluid at a flexible needle hub on a proximate end of the flexible needle prior to disposing the anti-restriction member of the flow element into the inner flow path of the flexible needle.

15

22. The method of claim 19, further comprising prior to inserting the distal end of the flexible spinal needle assembly through dura mater and into the intrathecal space of the subject, preparing the skin of a patient at an injection site; applying local anesthetic at the injection site; and inserting the distal end of the flexible spinal needle assembly through the prepared injection site.

20

23. The method of claim 19, wherein the flow element comprising: a body having an internal flow path for conducting a fluid through the flexible needle; and the anti-restriction member having an elongated body, a proximal end coupled to the body within the internal flow path, and a distal end to facilitate disposing at least a portion of the elongated body within the inner flow path of the flexible needle.

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24. A process for producing a flow element comprising:
forming an anti-restriction member having an elongated body, a proximal end and a
distal end, the elongated body configured for disposing at least a portion thereof
by way of the distal end within a flexible needle; and
5 securing the proximal end of the anti-restriction member to a body having an internal
flow path for conducting a fluid through a flexible needle.

25. The process for producing a flow element of claim 24, wherein securing
the proximal end of the anti-restriction member to the body comprises injection molding
10 the body about the proximal end of the anti-restriction member, and forming the
anti-restriction member having the elongated body comprises forming the
anti-restriction member having plurality of elongated bodies, at least one elongated
body comprising a plurality of wires.

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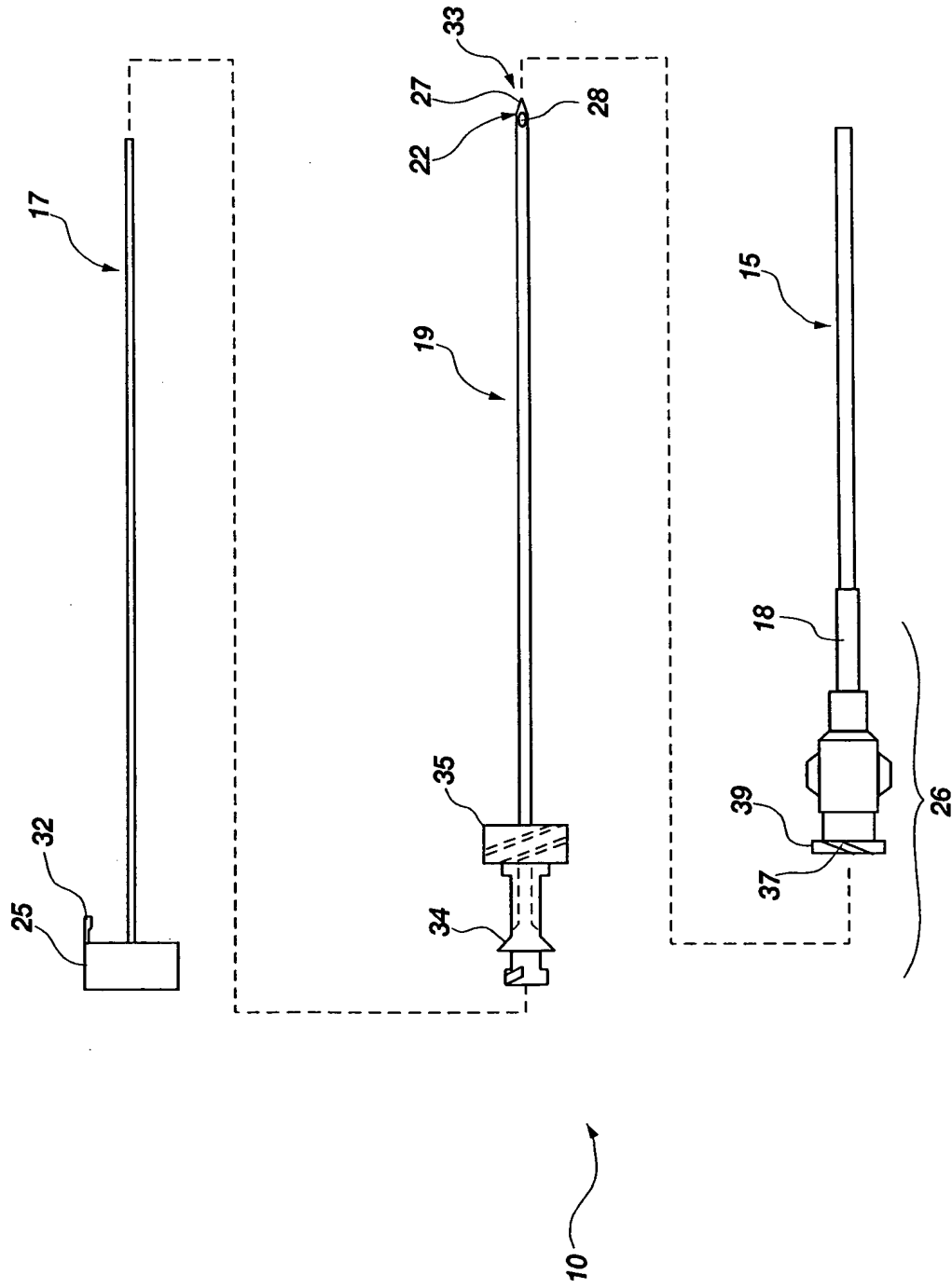
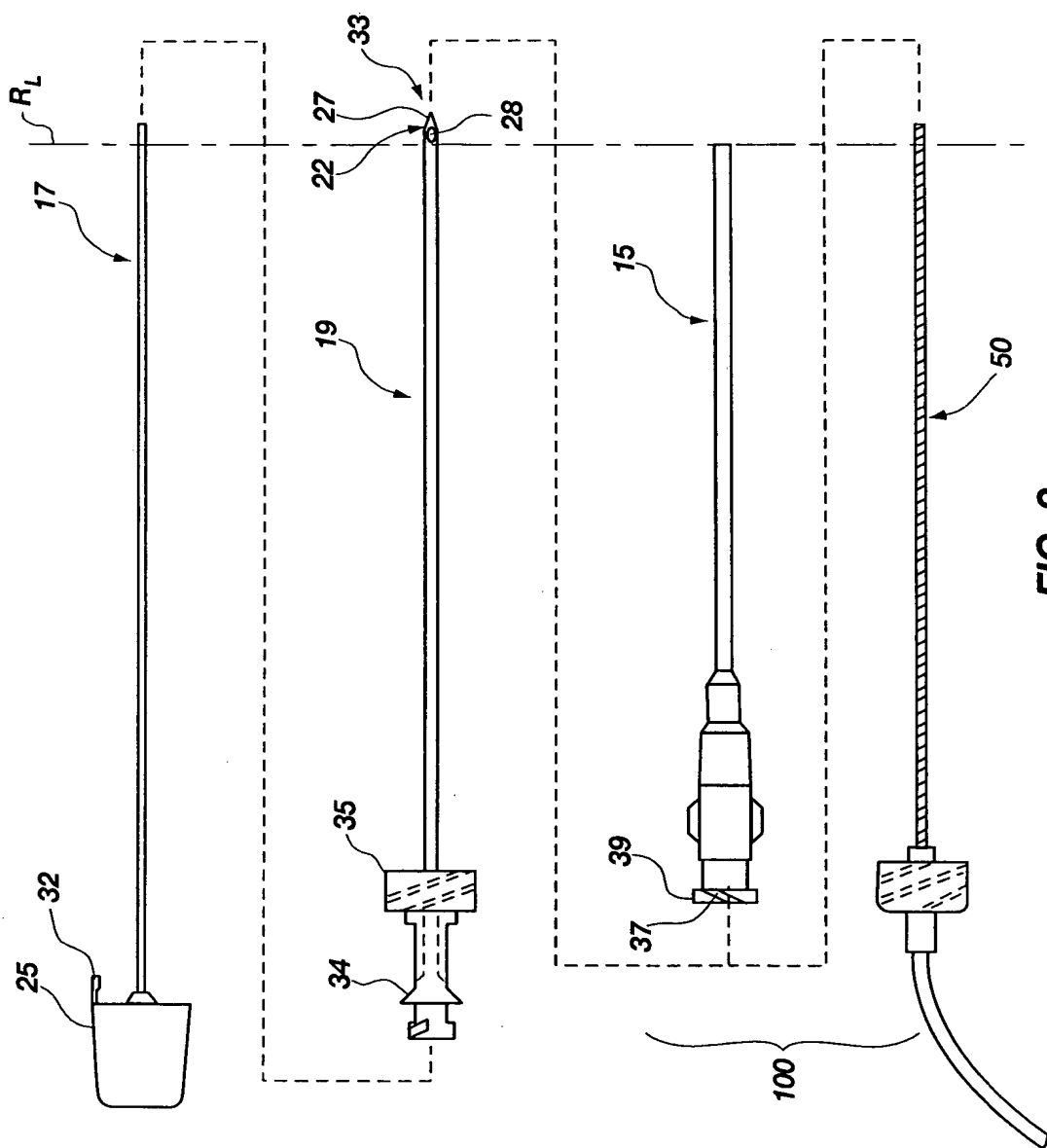


FIG. 1



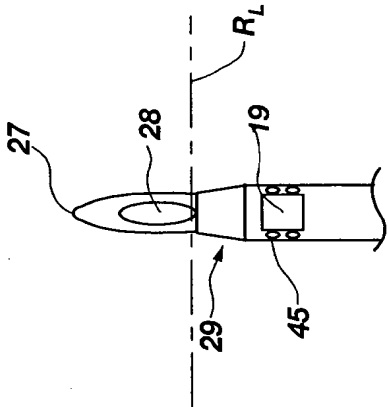


FIG. 4

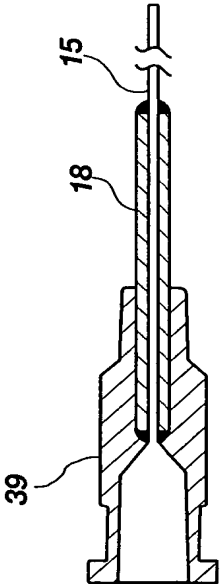
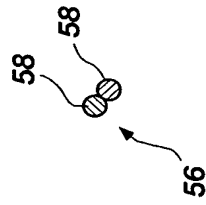
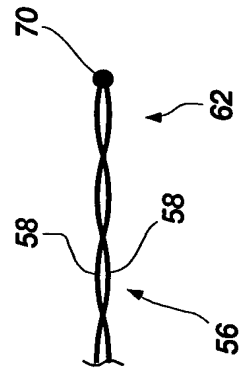
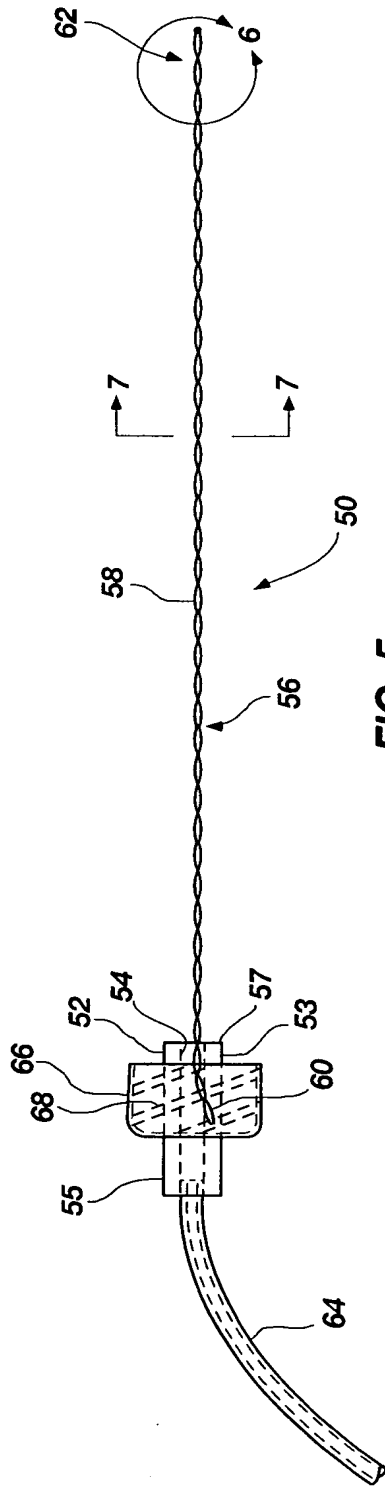


FIG. 3



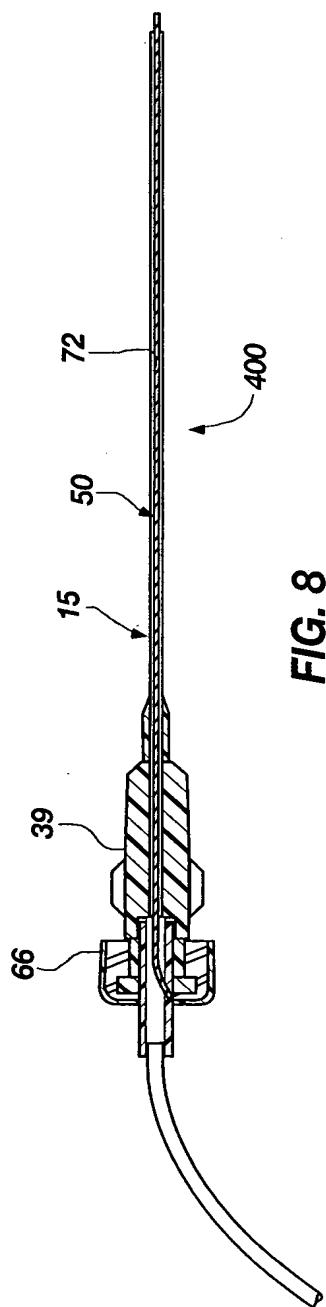


FIG. 8

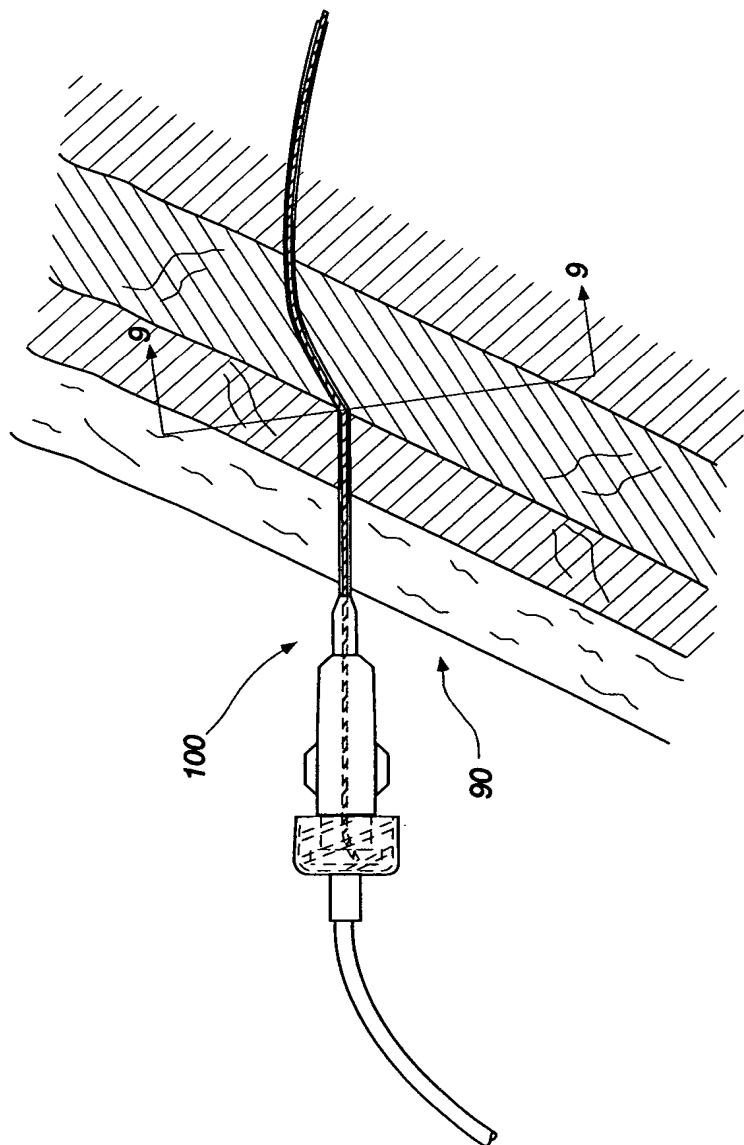


FIG. 9

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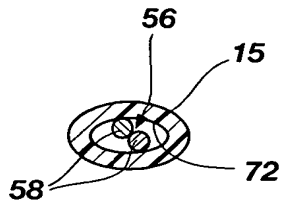


FIG. 10

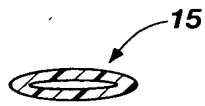


FIG. 11

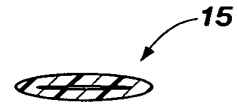


FIG. 12

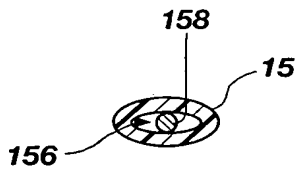


FIG. 13

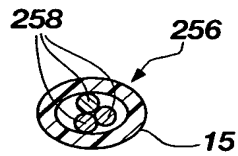


FIG. 14

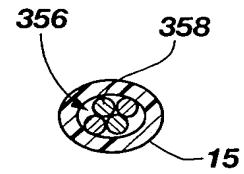


FIG. 15



FIG. 16



FIG. 17



FIG. 18

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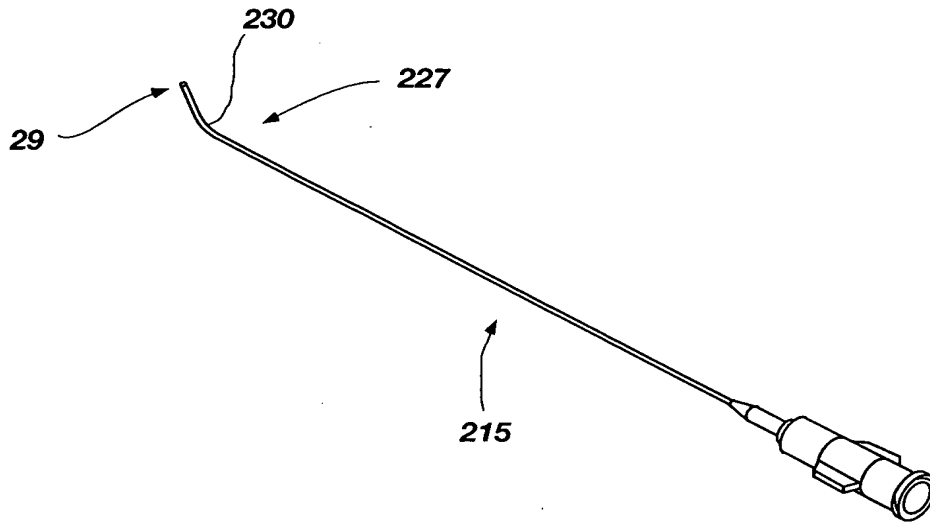


FIG. 19